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November 18, 2016

VIA ELECTRONIC FILING (ECFS)

Marlene H. Dortch, Secretary
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

**Re: *Ex Parte* Presentation
ET Docket No. 13-84**

Dear Ms. Dortch:

On November 16, 2016, representatives of Sensormatic Electronics, LLC (“Sensormatic”) met with staff of the FCC’s Office of Engineering and Technology to discuss Sensormatic’s position in the above-referenced proceeding. A complete list of attendees is attached as Exhibit 1. During the meeting, Sensormatic provided background on the company and its electronic anti-theft technology; discussed its support for the adoption of the IEEE EMF standard rather than the ICNIRP limits; described how this same issue was addressed in Canada, described its commitment to medical implant patient safety; and provided an update on improvements in medical implant technology, including compatibility with MRI scans; and responded to certain points raised by AAMI in this proceeding. Attached as Exhibit 2 is the handout provided at the meeting.

Please feel free to contact the undersigned if you have any questions.

Very truly yours,

Glenn S. Richards
Counsel for Sensormatic

Attachments

cc: (via email)
See Exhibit 1

Exhibit 1

Attendees

FCC Office of Engineering and Technology

Martin Doczkat (by phone)
Rashmi Doshi (by phone)
William Hurst (by phone)
Ed Mantiply
Bruce Romano

For Sensormatic Electronics, LLC

Ian Brooker (by phone)
Olin Giles
Paul Griffiths (by phone)
Jose Hernandez
Hap Patterson
Glenn Richards, Pillsbury Winthrop Shaw Pittman, LLP
Kenneth Taber, Pillsbury Winthrop Shaw Pittman, LLP

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Ex-parte Presentation for the
Federal Communications Commission
ET Docket 13-84 and ET Docket 03-137
Nov 16th, 2016

The Purpose of this Ex-Parte Meeting

- (1) Discuss the importance of the FCC selecting the proper EMF human exposure safety standard
- (2) Address why the FCC should reject AAMI's request to impose the ICNIRP 1998 Reference Levels

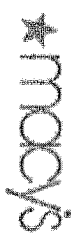
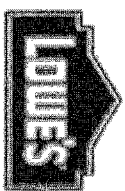
Agenda:

- Introduction to Sensormatic and its EAS technology
- Why the FCC should choose the IEEE EMF standard
.....or await the outcome of IEEE ICES SC-6
- Update on the situation in Canada
- Sensormatic's commitment to medical implant patient safety
- Improved EMI immunity
- Why the FCC should reject AAMI's request for ICNIRP 1998 RLs

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The World's Leading Provider of Electronic Anti-Theft Systems

Walmart *



JCPenney



CORIEFIEL

M&S
EST. 1884

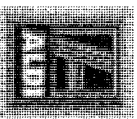
Dia Z



MANGO

TJ-MAXX[®]

BOSS
HUGO BOSS



INDITEX

METRO Group



H&M

PRINTemps



NorgesGruppen



charlotte
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new balance

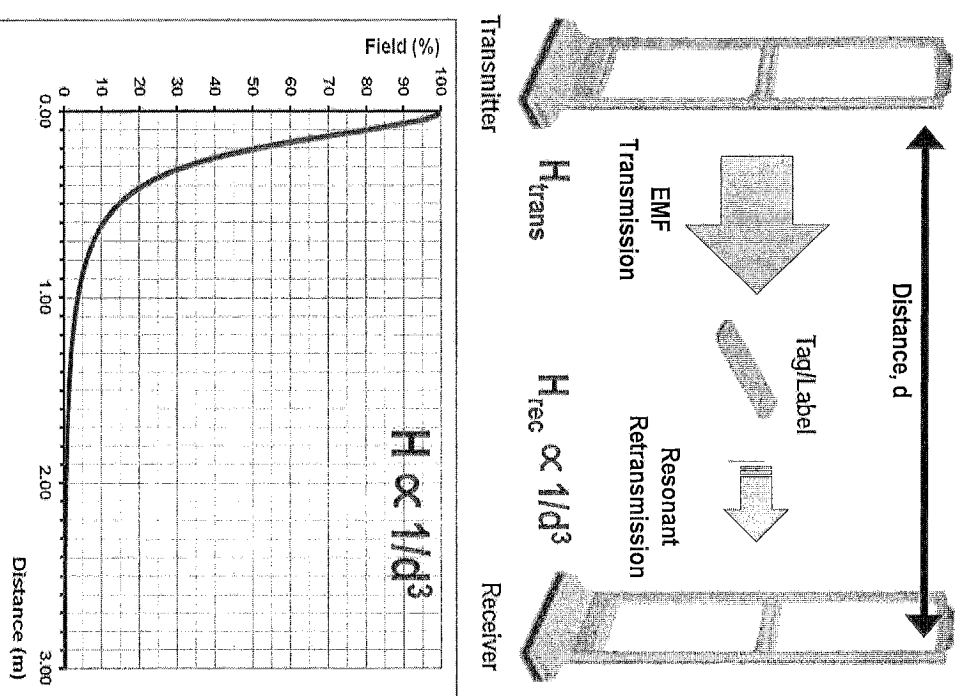
**Deters theft which costs consumers \$33 billion pa
\$400+ annually in costs for the average U.S. Family**

* The companies listed are examples of our global customers. All trademarks and service marks set forth above are the property of their respective owners

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Why can't Sensormatic reduce the EMF level of its EAS systems ?

- The customer's operation determines the system width needed.
 - Retailers like Home Depot and Lowe's require nine-foot openings for pallets of lumber.
 - Department stores like Macy's feature wide entrances with same nine-foot openings
 - UltraMax is a near-field inductive system.
 - The EMF level is attenuated in accordance with the "inverse cube law" of reactive near-field transmission
- $H \propto 1/d^3$
- Reducing field levels necessarily means, by simple physics, giving up reliable tag detection or sacrificing system width.



Once the system width is known, the EMF level required is inescapably set by the link-budget

The FCC should adopt the IEEE C95 Standards

- The IEEE standards are consensus-based, safe and based on science
 - The C95 set of standards contain limits, traceable to scientific findings, with justifications, measurements and safety programs
- Using IEEE is consistent with:
 - National Technology Transfer and Advancement Act of 1995
 - OMB Circular No. A-119 re: Federal use of voluntary consensus standards
- The ICNIRP Guidelines, by contrast
 - Were developed by a small, closed group
 - Basically a technical paper published in a Journal
 - No separate limits for body limbs....treats all body parts the same
- ICNIRP Reference Levels are Not Maximum Limits (& Never Have Been)
 - RLS are only provided for measurement ease... not as a limit
 - BRs allow higher EMF emission level but need dosimetric modeling for compliance

***At a Minimum, allow IEEE Limits for
Short-Term, Transitory Exposures***

ICNIRP 1998 is now replaced by ICNIRP 2010 below 100 kHz

- In relation to the 2010 RLS ICNIRP, itself, admitted that
 - “Defining reduction factors is to a large extent a matter of expert judgment”
 - “An additional reduction factor of 3 was applied to these calculated values to allow for dosimetric uncertainty” *
- **Consensus:** ICNIRP 1998 RLS were deeply flawed and impractical
 - ICNIRP 1998 RLS were so low that low frequency emitters could not meet them
 - ICNIRP 2010 allows a 4.2 times increase over ICNIRP 1998 general public RLS
 - ICNIRP 2010 BRs effectively allow greater emissions than given by RLS
 - ICNIRP 2010 BRs still have large safety margins at low frequencies – *RLs more so*
- IEEE and ICNIRP differ
 - General public BRs differ only by $\approx 1.5X$, yet
 - ICNIRP 1998 general public RLS are $\approx 32X$ lower than equivalent IEEE MPEs and
 - ICNIRP 2010 general public RLS are still $\approx 8X$ lower than equivalent IEEE MPEs
 - The main difference is in the dosimetry of RLS

* “ICNIRP Guidelines For Limiting Exposure To Time-Varying Electric And Magnetic Fields (1 Hz – 100 kHz)”, Health Physics 99(6):818-836; 2010

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Many Dosimetric Uncertainties with ICNIRP

- Dosimetry issues with ICNIRP have recently been outlined in two separate papers in *Health and Physics* (Rob Kavet* and Pat Reilly**)
- For the first time, ICNIRP is now communicating with IEEE ICES

- IEEE ICES has now formed SC-6 to:

*“resolve uncertainties related to numerical models that calculate electric fields induced within the body from EMFs”****

- Inspired by Pat Reilly, the recognized LF dosimetry expert.
- Chaired by Dr. Hirata of Japan
- FDA has three representatives on SC-6

FCC May Want to Await the Outcome of ICES SC-6

* “Uncertainty: Unpredictable, Irregular Field Coupling To Pregnant Women”, *Health Physics* 109(1):555-565, 2015

** “Human Exposure Standards in The Frequency Range 1 Hz To 100 kHz: The Case For Adoption Of The IEEE Standard”, *Health Physics* 109(1):555-565, 2015

*** “Time-Frequency Spectral Density: Present and Agenda Of The IEEE International Commission on Electromagnetic Safety”, *Health Physics* 112 Pt 1B:413-414, 2015

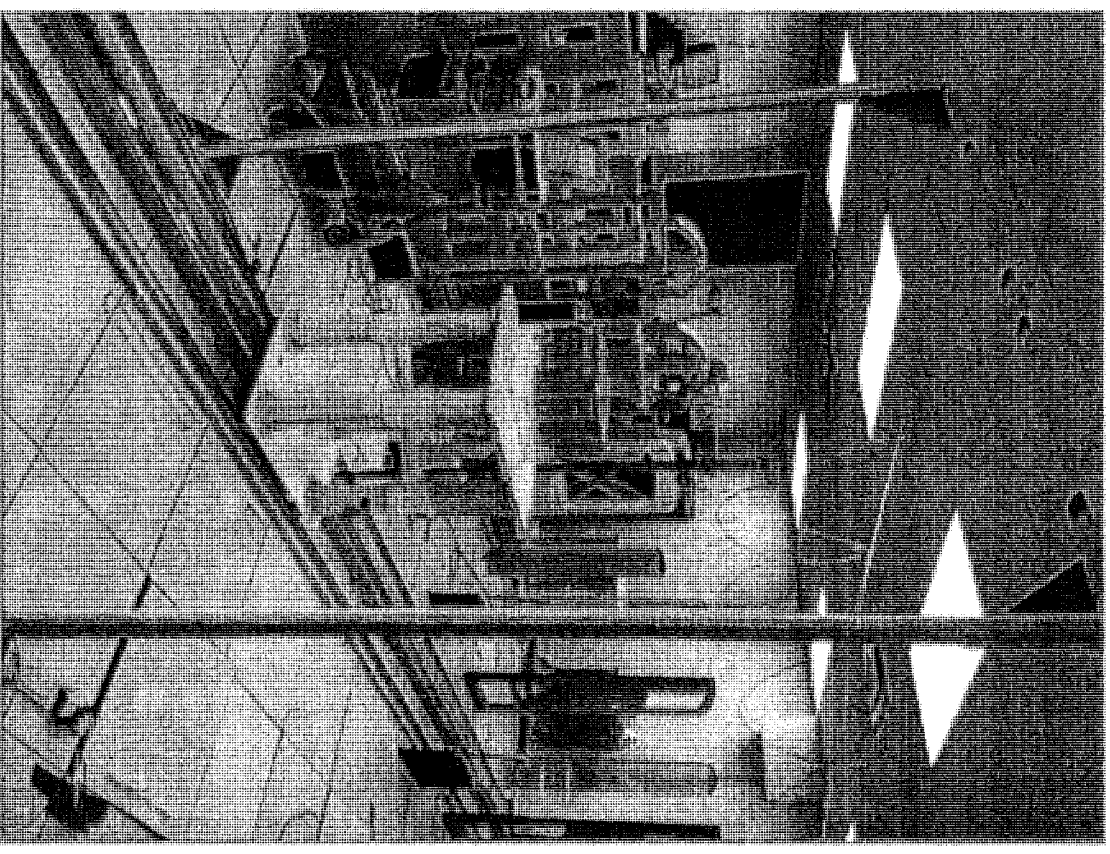
Canada Recently Adopted A Code Modified From ICNIRP 2010 BRs

- Canadian Safety Code 6 (SC6) specifies the EMF human exposure limits
 - Covers 3kHz upwards
 - SC6 based on ICNIRP 2010 BRs at Low Frequency; not the 1998 nor 2010 RLS
- Canada determined that the ICNIRP RLS have excessive safety margins
- SC6 allows Low Frequency Reference Levels of:
 - 90 A/m for uncontrolled environments
 - 4.3 times ICNIRP 2010 general public RLS and 18 times ICNIRP 1998 general public RLS
 - 180 A/m for controlled environments
 - 2.3 times ICNIRP 2010 occupational RLS and 7.4 times ICNIRP 1998 occupational RLS
- The new RSS-102 LF procedure also has relaxations for limb exposures
 - Reflecting the proven reduced coupling into the limbs
 - *Better Dosimetry*

***Health Canada Recognized the Flaws in ICNIRP 2010
...and Addressed Them***

Sensormatic's Commitment to Medical Implant Patient Safety

- Instrumental in establishing the EAS/Medical Device test center 20+ years ago, in 1995, at the Georgia Tech Research Institute (GTRI)
 - Multiple EAS Systems present
 - New EAS Systems can be tested
 - New PM/ICD designs routinely tested at GTRI; protocol required by FDA
- Funded multiple patient studies by renowned cardiologists
- Regular discussions, joint studies with implant manufacturers, over many years



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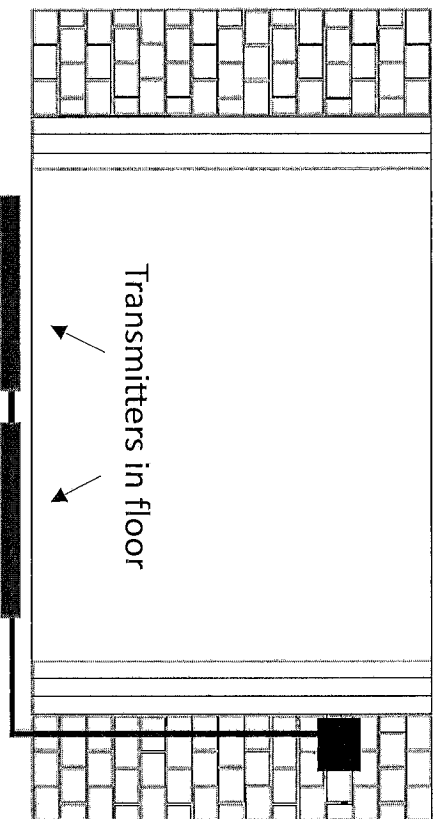
FDA has Evaluated Medical Implant/EAS Interactions

- Extensive evaluations of EAS and PM/ICD interactions in the FDA's laboratory and through the MAUDE database
- FDA held a public EAS/PM inquiry in 1998, concluded:
 - “Likelihood of EAS interference is low”
 - “Vast majority of events mild....little effect”
 - Endorsed “Don’t Linger, Don’t Lean” advice to patients
 - Lauded Sensormatic’s cooperation with device manufacturers
- Since then:
 - Favorable GTRI test results on non-pedestal systems
 - A broad consensus that PM/ICD EMI immunity is improving
 - Introduction of more resilient, MRI compatible devices

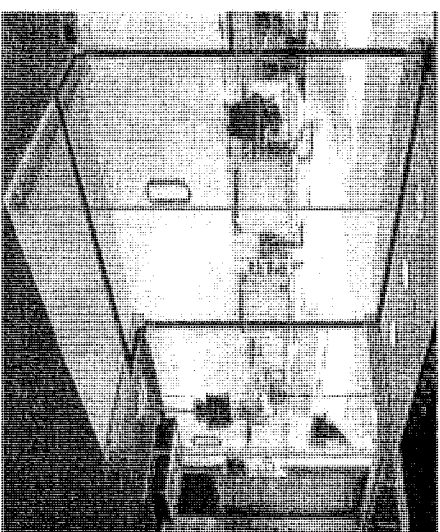
FDA Advice + Innovation is Working

Recent GTRI Tests on Invisible EAS Systems

Floor Systems – 9% of Installs



Door Loops – 2% of Installs



- Systems installed in the floor or door loops have been offered for many years....not a recent trend; most retailers, however, prefer visible pedestals for deterrent effect
- **No interactions** (normal therapy) even w/cumulative worst case GTRI tests
 - Included weak EMI rejection devices in the unipolar mode, at max sensitivity
 - Patients in a wheelchair or sitting on a bench still OK both in an upright or in a slouched position

“Invisible Systems” Pose No Risk

Response to Comments by AAMI

- Invisible systems in floors and walls are not new and, independent testing shows, pose no risk
- Sensormatic's systems are labeled per FDA guidelines; the company has an active program to monitor compliance
- AAMI erroneously refers to the ICNIRP 1998 RLS as the maximum or MPE limits..... the BRs are the actual limit
- AAMI has requested NEPA 1969 be used
 - NEPA was not discussed in the FCC NOI or earlier public comments
 - An improper attempt to bring EMC into this Proceeding
- FDA's MAUDE Database does not show major interactions between pacemakers and EAS
 - There are only 2 instances with a pacemaker from 2009-2016; none for ICDs (No patient harm in either incident)
- MRI compatible devices are now possible

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MRI compatible PM/ICDs are Driving the Market to Even More Resilience

- Patients require PM/ICDs that allow safe MRI scans
 - Most people will need MRI scans as they age *
- MRI compatible devices
 - designed to operate safely under specified MRI scanning conditions
 - MRI compatible PMs now offered by the four leading manufacturers....
 - ICDs currently offered by two manufacturers
 - require bipolar leads..... dramatically reducing EMI, due to the 15X reduction in loop area
 - Some are capable of 3 Tesla MRI scans - way above EAS levels
- Georgia Tech Research Institute data shows **no PM/ICD interactions** with EAS with the new MRI compatible devices

***Market Penetration of New MRI compatible Devices
Expected to Quickly Approach 100% *****

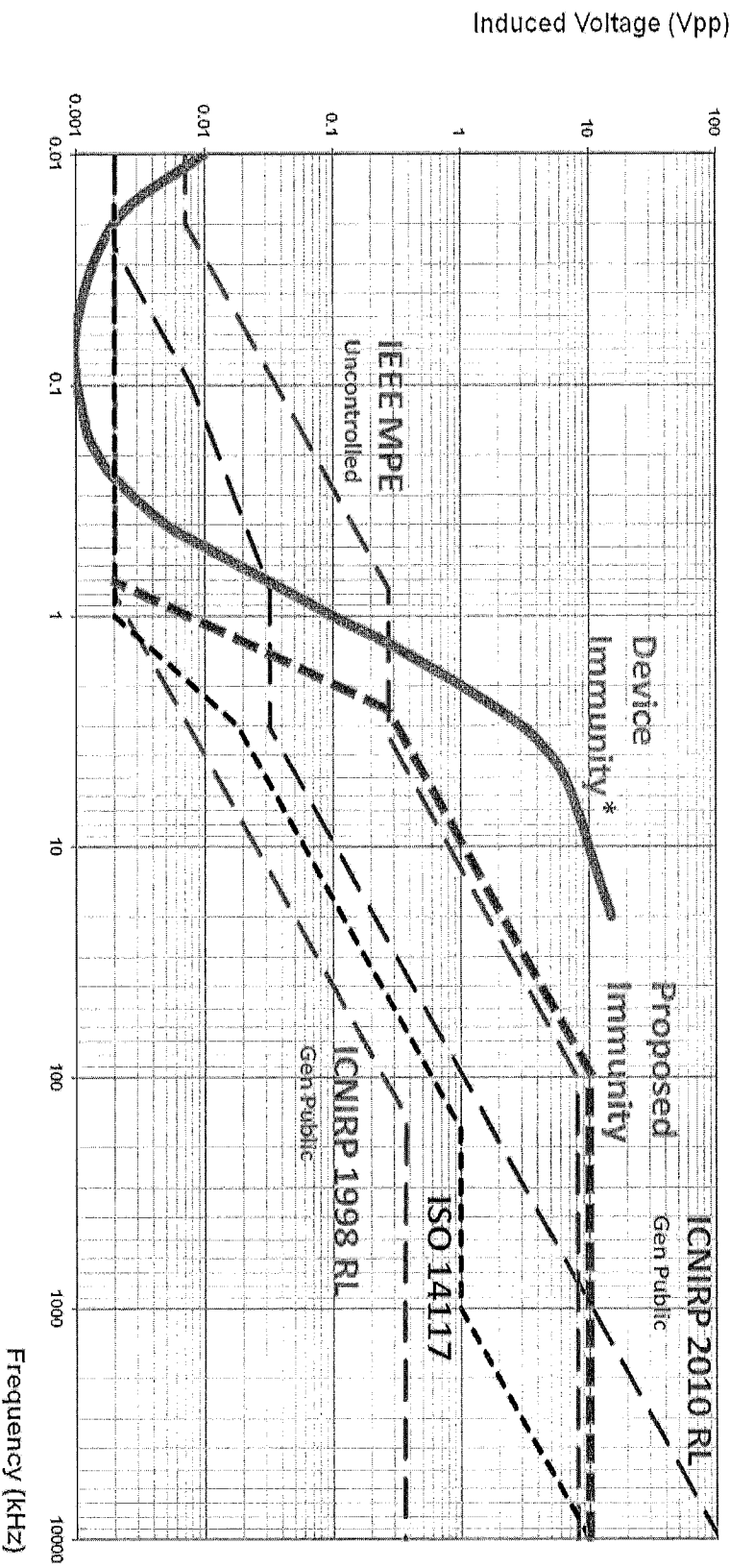
* "MRI-compatible pacemakers: current perspectives", Fierman A et al, Medical Devices: Evaluation and Research, 2014;7(1):5-10; Cross printed 2014
** Global MRI Compatible Market: Prospects to 2015", The Business Research Company, Executive Summary, 2014.

EMI Resilience has Improved and Could, if Necessary, be Even Better

- *Technology Already Available* to virtually eliminate PM/ICD EMI:
 - Avoid return paths to the case of the implant by using bipolar connections
 - avoids large effective interference induction loops through the body
 - Isolate device receiver from the pulse generator
 - avoids rectification and AM detection ahead of filtering
 - Use symmetrical limiting devices to maintain signal symmetry
 - Provide diode voltage protection on all inputs
 - Techniques effective on CW, AM and pulsed interfering signals
 - Very large $10\text{-}20\text{V}_{\text{p-p}}$ interference signals have no affect on device therapy
- Devices successfully used similar concepts
 - E.g. Implantronik in 1990s
 - Colen Patent, US 5,170,806 ; published 1992, now in the public domain
 - Hundreds of devices built using such techniques
- Proprietary techniques & technology may differ but results are the same...
 - ...Improved Immunity

Possible EMI Performance

Induced Voltage Comparison
(Field equivalent based on Unipolar with ISO14117 loop size)



- A possible immunity curve which is likely more representative
 - Below 800Hz and above 10MHz – could match present ISO 14117
 - Between 1kHz-10MHz would actually be close to the equivalent IEEE MPES

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AAMI Request to Further Limit EMFs is Unnecessary and Unwarranted

- EMI potential has long been known – handled by:
 - Short term exposure protection
 - Device labeling and “*Don’t Linger, Don’t Lean*” guidance
 - Temporary exposure protection built-in for IEEE MPE exposure levels
 - Greater use of Bipolar and Multipolar devices
 - MRI compatible implants
- Data doesn’t Support AAMI’s Request
 - FDA’s own MAUDE database with over 250,000 new entries/year shows only two EAS-related entries in the 7 years to September 2016,
 - Neither presented dangers to patients
- MRI compatible Devices
 - Greatly enhanced resilience
 - Many now available and being implanted
 - Expected to be $\approx 100\%$ of new implants

***No public health issue justifies AAMI’s demand for the
ICNIRP 1998 RLS***

Can Products Meet ICNIRP 2010 BRs & Canada SC6 ?

- Canada SC6 uses an RL much more aligned with ICNIRP BRs
 - SC6 and RSS-102 still result in a reduction in product & installation performance
 - Restricts wide openings for larger entrances
 - Detracts from appearance in wide exit store fronts
 - SC6 and RSS-102 grandfather existing installations
- While undesirable, products may be able to meet these rules provided:
 - The ICNIRP 1998 or 2010 Reference Levels (or lower) are not made into limits
 - Assessment to Basic Restrictions is allowed
 - Limb exposures are properly taken into consideration
 - Sufficient time is allowed for transition to allow for possible re-designs
 - Existing installations are grandfathered

But: End Users will have to accept limitations on product performance for new products and installations

***Meeting SC6 is a Challenge.
Sensormatic Encourages the FCC to Select
the IEEE C95 Standard Instead***

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Sensormatic Systems are part of the environment

- EAS systems are everywhere...
 - A well known part of the environment
 - EAS EMF levels unchanged for decades (with no plans to increase levels)
- Medical device manufacturers are fully aware of EAS systems and have successfully designed their devices accordingly
 - “No significant impact” on the health or safety of patients with medical implants
- Nearly a million systems operating globally

Decades of Safe Operation

Billions of Safe Passages

Sensormatic

***Use of the 1998 Reference Levels
as limits
Would Preclude The Use Of The
<100KHz Spectrum
By Radio and Inductive Devices***